

WHAT IS CLAIMED IS:

1 1. A method for inhibiting hyperplasia at a vascular treatment site, said
2 method comprising:
3 directing vibrational energy at the vascular treatment site, wherein a scaffold
4 structure has been implanted at said site, said scaffold structure being coated with a
5 pharmaceutical agent which is released into the site over time, wherein directing vibrational
6 energy comprises positioning a transducer on a catheter at the vascular treatment site and
7 driving the transducer to emit the vibrational energy at the same time as the scaffold structure
8 is implanted.

1 2. A method as in claim 1, wherein the vibrational energy is directed at
2 the site at the time of implantation of the scaffold structure at a frequency and thermal index
3 which will inhibit an acute phase of the hyperplasia, wherein the pharmaceutical agent is
4 released over a period of at least one week following implantation to provide a longer term
5 inhibition.

1 3. A method as in claim 2, wherein the vibrational energy does not cause
2 significant cavitation in a wall of the blood vessel.

1 4. A method as in claim 2, wherein the vibrational energy causes a
2 temperature rise below 10°C in the wall of the blood vessel.

1 5. A method as in claim 2, wherein vascular smooth muscle cells at least
2 mostly remain viable but in a quiescent state in the neointimal layer after exposure to the
3 vibrational energy.

1 6. A method as in claim 2, wherein migration of vascular smooth muscle
2 cells into the neointimal layer is not substantially inhibited.

1 7. A method as in claim 2, wherein viability of vascular smooth muscle
2 cells in a medial layer of the blood vessel is not significantly inhibited.

1 8. A method as in claim 2, wherein the vibrational energy has a frequency
2 in the range from 20 kHz to 5MHz.

1 9. A method as in claim 8, wherein the intensity is in the range from 0.01
2 W/cm² to 100 W/cm².

1 10. A method as in claim 9, wherein the frequency and intensity are
2 selected to produce a mechanical index at the neointimal wall in the range from 0.1 to 50.

1 11. A method as in claim 2, wherein the vibrational energy is directed
2 against the implantation site with a pulse repetition frequency (PRF) in the range from 10 Hz
3 to 10 kHz.

1 12. A method as in claim 2, wherein the energy is directed against the
2 implantation site with a duty cycle in the range from 0.1 to 100 percent.

1 13. A method as in claim 1, wherein the vibrational energy is directed at a
2 mechanical index selected to effect or promote release of the pharmaceutical agent from the
3 implanted scaffold structure.

1 14. A method as in claim 13, wherein the frequency is in the range from
2 20 kHz to 5 MHz and the intensity is in the range from 0.01 w/cm² to 100 W/cm².

1 15. A method as in claim 1, wherein the vibrational energy is directed at a
2 mechanical index selected to condition the vascular wall to enhance uptake of the
3 pharmaceutical agent.

1 16. A method as in claim 15, wherein the frequency is in the range from
2 300 kHz to 3 MHz and the intensity is in the range from 0.1 w/cm² to 20 W/cm².

1 17. A method as in claim 1, further comprising directing vibrational
2 energy at the vascular treatment site at least one additional time.

1 18. A method as in claim 17, wherein vibrational energy is directed at the
2 vascular treatment site at least once at the time of implanting the scaffold structure and at
3 least once one day or longer following implantation.

1 19. A method as in claim 1, wherein directing vibrational energy
2 comprises externally generating vibrational energy and directing the vibrational energy
3 transcutaneously to the vascular treatment site.

1 20. A method as in claim 19, wherein externally generating the vibrational
2 energy comprises focusing an externally generated acoustic beam at the vascular treatment
3 site.

1 21. A method as in claim 1, wherein the pharmaceutical agent comprises
2 an agent selected from the group consisting of:
3 anti-coagulants (heparin, hirudin, GpIIB/IIIA inhibitors), anti-proliferation
4 agents (paclitaxol, nitric oxide), anti-inflammatory agents (dexamethasone,
5 methylprednisolone), antibiotics (rapamycin) and anti-oxidants (probucol).

1 22. A method as in claim 1, wherein the pharmaceutical agent comprises a
2 nucleic acid sequence.

1 23. A method as in claim 22, wherein the nucleic acid sequence comprises
2 genes expressing VEGF, thymidine kinase, eNOS and antisense oligonucleotides such as c-
3 myc.

1 24. A method as in claim 1, wherein the pharmaceutical agent is directly
2 layered onto the scaffold structure.

1 25. A method as in claim 1, wherein the pharmaceutical agent is dispersed
2 in a biodegradable matrix applied to the surface of the scaffold structure.

1 26. A method as in claim 25, wherein the biodegradable matrix comprises
2 polylactic acid or polyglycolic acid.